GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3932
ANSWERED ON:20.04.2005
CLINICAL TRIALS OF LETROZOLE
Kripalani Shri Srichand

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a case has been filed against Sun Pharma manufacturer of letrozole for using the drug as clinical trials without the knowledge of DCGI for infertility; and

(b) if so, the details thereof and the action taken/proposed to be taken against the clinics who are still engaged in using letrozole (anti-cancer drug) for infertility illegally?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a)& (b) : Letrozole has been approved in the country as 1st and 2nd line therapy of breast Cancer for manufacture by M/s. Novartis and also by M/s. Sun Pharma, Natco Pharma & Cipla Ltd. etc.

Reports had, however, been received about the use of Letrozole by some Gynecologists for the treatment of infertility based on internationally published reports in Medical Journals about its usefulness in induction of ovulation. The issue was examined in this Ministry in consultation with experts. Such use of drug by Medical Practioners for an indication, not yet officially approved is considered as `Off label use of drugs`, and is practiced all over the World by doctors.

However, the firms including M/s. Sun Pharmaceuticals Ltd., M/s. Dabur India Ltd. were strongly warned not to promote their Letrozole formulations for the treatment of infertility in Indian women.